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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/894,767	02/23/1998	WERNER WEITSCHIES	SCH1526	9325

23599 7590 06/18/2002

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EXAMINER

DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/18/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/894,767

Applicant(s)

WEITSCHIES ET AL.

Examiner

Pensee T. Do

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 22-32 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6, 7, 26-32 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 8-18, 22-25, 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

The request filed on March 19, 2002 for a Continued Examination (RCE) under 37 C.F.R. 1.114 based on parent Application No. 08/894,767 is acceptable and an RCE has been established. An action on the RCE follows.

Claims Status

Claims 1, 2, 4, 5, 8-18, 22-25, 39 are pending. Claims 3, 6, 7, 26-32, 35-38 are non-elected.

Election/Restrictions

Applicants traverse that all four groups of claims employ the same or corresponding special technical feature, that is, the use of ferromagnetic or ferromagnetic substances as labels to detect substances either in vitro or in vivo. In all four groups of claims, the technical features are materials labeled with magnetic substances are detected through the use of typical magnetization detection techniques.

The special technical feature that the applicants define is well known in the art and is taught by the Japanese patent JP3220442 (filed by applicant) which teach a method of determining the concentration of antibody or antigen in a liquid sample, comprising suspending magnetic fine particles fixed with antibody or antigen binding specifically with the analyte, the antigen or antibody, in a liquid sample containing the analyte, antigen or antibody, to cause agglutination of the magnetic fine particles by antigen-antibody reaction, applying a magnetic field, and measuring the remanent

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magnetic flux density of the agglutinated matter to determine the particle size of the agglutinated matter.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objection

Claim 22 is objected to because of the following informalities: claim 22 depends on a non-elected claim 3. Claim 22 is required to be dependent upon an elected claim or in an independent form. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 5, 8-18, 22-25, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In all dependent claims, please change "A process" in line 1, to –The process— for proper antecedent basis.

Claim 1 is unclear as to whether or not the ferromagnetic/ferromagnetic substances are labels containing ligand which binds to the analytes in the sample.

Claims 1 and 2 ^{are missing method steps} ~~lack determination step~~. There is no positive recitation of a contact step between reagents and sample or a correlation step that relates the remanence magnetization to the presence of analyte. The claims are also unclear as to what is being detected to determine the presence of analyte. The claims only recite "determining remanence magnetization" which has no association with the presence of

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analytes. The claims are also unclear as to how the magnetization determines the presence of analyte, e.g. detecting a rise or drop in this magnetization to detect the analytes.

Claims 4, 5 lack antecedent support for the structure-specific substances" which has not been introduced in claim 1. Claim 4 is confusing as to whether the samples contain analytes. It seems as the analytes are labeled with magnetic substances in one medium/solution and the structure-specific substance are added to sample in another medium/solution.

Claim 8 is unclear of how the sample is moved during measurement, e.g. the means, e.g. detection sensor ?, for moving the sample during measurement.

Claim 11 recites "a sample to be measured". Is this "sample" the same as the one recited in claim 1? If not please distinguish the two.

Withdrawn Rejection(s)

Rejections under 35 USC 102(b) and 103(a) are withdrawn herein.

Response to Arguments

Applicant's arguments filed February 21, 2001 have been fully considered but they are not all persuasive.

With respect to the objection to claim 22, applicants argue that it is not fully understood why this claim has been singled out for this objection, since various other claims also depend upon non-elected claims.

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Claim 22 is the only claim which depends upon a non-elected claim. No other pending claims, among claims 1, 2, 4, 5, 22-25, and 39, depend on a non-elected claim. Claim 22 is required to be in an independent form or dependent upon an elected claim.

Remarks

Claims 1, 2, 4, 5, 8-18, 22-25, 39 are free of prior arts.

The prior arts do not teach a method of qualitative and/or quantitative detection of analytes in a liquid and/or solid phase homogeneous assay, comprising determining the remanence magnetization in said homogeneous assay after addition to a sample of a stable or quasi-stable ferromagnetic or ferromagnetic substances.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri from 7 a.m. to 4 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Pensee T. Do
Patent Examiner
June 13, 2002



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800/641